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(54) Device for an active implant

(57) The invention relates to an active implant comprising a hermetically sealable capsule consisting of a first part (111, 112) and a second closing part (112, 212), the capsule thereby being devised to hold a battery unit (130, 230), an electronics unit (120, 220), means (131, 132, 231, 232) for electrically connecting the battery to the electronics unit and contacts (180, 280) arranged on the exterior of the capsule for connection to electrodes, whereby:
the first part (111, 211) is made, at least in part, of a rolled composite sheet or plate and comprising one layer (114, 214) of which made of a biocompatible material and the second layer (113, 213) made of a diffusion-proof material which is essentially resistant to corrosive chemicals, the two layers being joinable by means of e.g. rolling, the layer made of biocompatible material constituting the outer wall of the capsule, the closing part (112, 212) contains a layer of the biocompatible material serving as the capsule's outer wall and a partition wall (140, 240), made of diffusion-proof material which is essentially resistant to corrosive chemicals, is arranged as to form a first essentially closed space for the power source (130, 230) in the first part (111, 211), a second space (118, 218) intended for the electronics unit (120, 220) thereby being formed between the wall closing off the capsule and the partition wall, a battery devised in a similar manner and a method for making same.

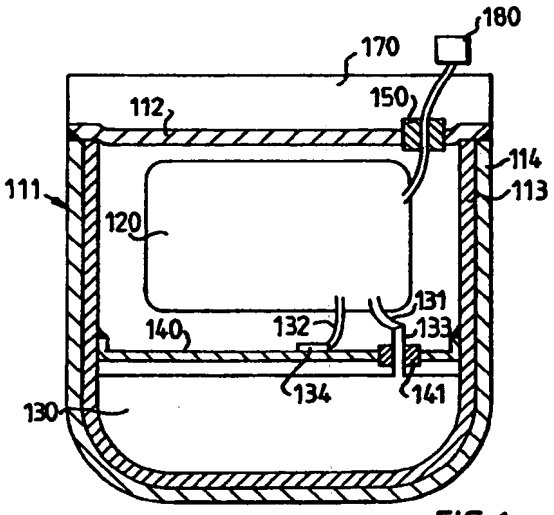

FIG. 1

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Description

The invention relates to a pacemaker or a defibrillator, an encapsulated battery unit/power source and a method for the manufacture of the same.

Battery unit in this context includes essentially all parts of the battery excluding the casing.

The aforementioned devices are intended for use as implants. The devices can encompass pulse-generating and, possibly, sensing circuits in addition to batteries. These device types are known in the medical art and used with good results.

There has always been some concern about the effect moisture, which surrounds the implanted device, could have on the device's casing, since the device inside the casing must be able to operate continuously for a number of years, impervious to surrounding human tissue, for reliable function. In the art, this is achieved by encapsulating the device in a hermetically sealed casing, as set forth in e.g. US,A,4 127 134, to prevent damage caused by e.g. increased internal pressure resulting from the emission of gas by the battery during operation.

The aforementioned devices must also be protected from damage inflicted by their electrical components. They are admittedly essentially inert, but batteries, capacitors etc. constitute potential risks if they are not carefully encapsulated.

US,A,5 144 946 describes e.g. a pacemaker in which a battery and an integral connective unit are arranged in a casing having two parts. The said unit comprises the electrical components, conductors for interconnecting the battery and electrical circuits and terminals for transmitting signals from the pacemaker to the patient. In one embodiment, the integral connective unit is enclosed in a capsule made of e.g. silicone rubber, i.e. the electrical components are insulated from the battery to protect the electrical components.

One example of encapsulation of non-inert components, a capacitor in this instance, in devices according to the above is described in US,A,5 131 388. This document also describes the importance of adapting the size of devices intended for use as implants. The document stipulates the use of a material with good corrosion resistance, such as stainless steel or titanium, for encapsulating the capacitor. However, encapsulation of a conventional aluminum electrolytic capacitor is involved in this instance.

Another problem to be considered with devices of this kind is the need to array a plurality of components during assembly in a manner which saves space and is satisfactory from the safety point of view.

In the art, it has proved necessary with devices of the above kind, which utilize lithium-iodine batteries, to encapsulate the battery because battery iodine could attack the electronics or external casing. However, titanium is not suitable for this casing, since titanium and even the titanium oxide which forms on it are attacked by iodine. So some other material must be found for battery encapsulation.

In order to protect the device from body fluids and achieve a device which is largely biocompatible, titanium is used to advantage for the external casing, since it has proved to be the most biocompatible material.

The object of the present invention is to achieve a device of the aforementioned kind which is reliable, i.e. which protects components and which is suitable for the environment in which it is to be placed.

An additional object is to achieve a device which is easy to assemble and seal.

An additional object is to achieve a device of the aforementioned kind with small dimensions.

According to the invention, the above objects are achieved according to the characterizing part of claim 1.

Preferred embodiments of the invention are set forth in the sub-claims.

The invention will now be described in greater detail, referring to the enclosed drawings which show preferred embodiments.

FIG. 1 shows a schematic cross-section of a first unipolar embodiment of the invention.

FIG. 2 shows a schematic cross-section of a second bipolar embodiment of the invention.

FIG. 3 shows a battery using the principle of the embodiment in FIG. 1.

FIG. 4 shows a battery using the principle of the embodiment in FIG. 2.

The active implant shown in FIG. 1 comprises a capsule made of two parts. A first part 111 is bowl-shaped and a second part 112 is arranged to seal the capsule. The capsule contains an electronics unit 120 of the kind used in these devices (not described here), a battery unit 130 and conductors 131 and 132 between the battery unit and the electronics unit. An end section 170 is arranged on the closing part 112.

According to the invention, the first capsule part 111 is made of a rolled composite plate or sheet comprising two layers, i.e. one layer 113 made of stainless steel and one layer 114 made of titanium. The stainless steel layer could naturally be replaced by some other suitable material, capable of functioning in concert with titanium, which is sufficiently dense and corrosion-resistant. The layer of titanium serves as the contact with the patient, and the stainless steel layer is arranged on the interior of the part 111. The closing part 112 can, as here, be devised in the shape of a flat, titanium lid which is welded to the bowl-shaped part. The lid could also be made from the same combination of metals as the bowl-shaped part. A battery unit 130 is arranged in a first part of the device. The battery unit is separated from the rest of the capsule by a partition wall 140 made of stainless steel, e.g. 0.3 to 0.4 mm in cross-section, arranged essentially parallel to the bottom of the capsule and sealingly welded to the interior of the bowl-shaped part. A lead-in 141 is arranged in the partition wall 140 for the battery's negative pole 133. In this example, the capsule serves as the positive pole, and a positive terminal 134 is arranged on the partition. The

partition 140 can also be made of a plurality of layers, as shown in the FIG., as long as the layer closest to the battery is a material of the same kind stipulated above.

So the layer 113 serves as the battery's casing and is in direct contact with one of the electrodes and the electrolyte respectively.

An electronics unit 120, for which the battery serves as a source of current/power, is arranged in the second part of the capsule.

A lead-in 150 is arranged through the closing part 112 for conductors from the electronics unit to contacts intended for connection to heart electrodes.

The active implant shown in FIG. 2 also has a capsule made of two parts. A first part 211 is bowl-shaped, and a second part 212 closes the capsule. The capsule contains an electronics units 220 of the kind used in such devices (not described here), a battery unit 230 and conductors 231 and 232 respectively between the battery unit and the electronics unit. An end piece 270 is arranged on the closing part 212.

According to the invention, the first capsule part 211 is made of a rolled composite plate or sheet comprising two layers of metal, i.e. a layer 213 made of stainless steel and a layer 214 made of titanium. The layer of titanium serves as the contact with the patient, and the stainless steel layer is arranged on the interior of the part 211. The closing part 212 can, as here, be devised in the shape of a flat titanium lid which is welded to the bowl-shaped part. The lid could also be made from the same combination of metals as the bowl-shaped part. A battery unit 230 is arranged in a first part of the device. This unit is separated from the rest of the capsule by a partition wall 240 made of stainless steel, 0.3 to 0.4 mm in cross-section, arranged essentially parallel to the bottom of the capsule, and lead-ins 241 and 243 are arranged in the partition wall 240 for the battery's poles. In this embodiment, the battery unit is electrically insulated from surrounding metal surfaces by a non-conductive layer 260.

An electronics unit 220, for which the battery serves as a source of power, is arranged in the second part of the capsule.

A lead-in 250 is arranged through the closing part 212 for conductors from the electronics unit to contacts intended for connection to electrodes.

In this embodiment, the capsule casing is not employed as one of the battery poles, and the battery is completely encapsulated in an insulating material which serves as the battery's casing encapsulating electrodes and electrolyte.

One embodiment of the invention also consists of two types of encapsulated battery units, devised essentially like the battery section in the two aforementioned embodiments. The batteries are shown in FIGS. 3 and 4.

The battery shown in FIG. 3 comprises a capsule with two parts. A first part 311 is bowl-shaped, and a second part 340 is arranged to close the capsule. A power source 330, e.g. a battery unit, is arranged in the capsule.

The first and second capsule parts 311, 340 are made of two layers 313, 314 of a rolled composite plate or sheet in the same way reported for the part 111 in the description of FIG. 1.

The second closing part 340 is preferably made of the same combination of materials as part 311 and sealed to the first part 311. A lead-in 341 is arranged in the second part for one of the battery poles. In this embodiment, the casing, or a part of the casing, serves as the other pole. So the layer 313 acts as the battery's casing and is in direct contact with electrode or electrolyte.

The power source shown in FIG. 4 comprises a capsule with two parts. A first part 411 is bowl-shaped, and a second part 440 is arranged to seal the capsule, e.g. by welding.

The first capsule part 411, is made of the same rolled composite plate or sheet comprising two layers of metal 413, 414 in the same way reported in the description of FIG. 1. The second capsule part 440 is e.g. made from the same metal as the outer layer of the first part. The second part may of course be made from the same metal plate/sheet combination as the first part.

The battery unit in the embodiment shown in FIG. 4 is electrically insulated from the casing/capsule by a non-conductive layer 460.

In the second part, lead-ins 441 and 443 are arranged for the battery's poles.

The device and method according to the invention described above, referring to the embodiments shown in the drawings, can naturally be modified within the scope of the attached patent claims with a view to the description and drawings.

Claims

1. An active implant comprising a hermetically sealable capsule consisting of a first part (111, 211) and a second closing part (112, 212), the capsule thereby being devised to hold a battery unit (130, 230), an electronics unit (120, 220), means (131, 132, 231, 232) for electrically connecting the battery unit to the electronics unit and contacts (180, 280) arranged on the exterior of the capsule for connection to electrodes, characterized in that: the first part (111, 211) is made, at least in part, of a material comprising at least two layers, the first layer (114, 214) consisting of a biocompatible material and the second layer (113, 213) consisting of a material which is essentially diffusion-proof and essentially resistant to corrosive chemicals, the two layers being joinable by means of e.g. rolling, the layer made of biocompatible material constituting the outer wall of the capsule, the closing part (112, 212) comprising at least the layer of the biocompatible material serving as the capsule's outer wall and a partition wall (140, 240), made of a material which is essentially resistant to corrosive chemicals, and

essentially diffusion-proof arranged so as to form a first essentially closed space for the battery unit (130, 230) in the first part (111, 211), whereat the partition wall (140, 240) and the first part (111, 211) constitutes the casing for the battery unit, said casing being an integral part of the capsule and whereat a second space (118, 218) intended for the electronics unit (120, 220) thereby being formed between the capsule-closing part (112, 212) and the partition wall (140, 240).

2. An active implant according to claim 1, **characterized** in that the essentially diffusion-proof material which is resistant to corrosive chemicals is one of the following: stainless steel, preferably 304L according to ASTM, nickel or Cr-Ni steel.

3. An active implant according to claim 1 or 2, **characterized** in that the biocompatible material is titanium.

4. An active implant according to any of the claims 1-3, **characterized** in that the battery unit (130) is arranged in direct contact with the first part's (111) second layer (113) which is facing the closed space, this second electrically conductive layer (113) thereby constituting one of the battery's poles (134) and is connected to the electronics unit (132), a lead-in (241) for the other pole (133) of the battery unit being arranged in the partition wall (140).

5. An active implant according to any of claims 1 to 3, **characterized** in that the battery unit (230) is arranged in the first closed space, insulated from the first part's layer (213) facing the closed space, the lead-ins (241, 243) for the battery unit's poles (143, 134) being arranged in the partition wall (240).

6. A battery comprising a first part (311, 411), a partition wall (340, 440) and a battery unit (330, 430), said first part and said partition wall forming the battery enclosure, **characterized** in that the first part (111, 211) is made at least in part of a material, comprising at least two layers, the first layer (314, 414) consisting of a biocompatible material and the second layer (313, 413) consisting of a material which is essentially diffusion-proof and essentially resistant to corrosive chemicals, the two layers being joinable by means of e.g. rolling, the layer (314, 414) made of the biocompatible material serving as the outer wall of the unit, the battery unit-closing partition wall (340, 440) being made of at least one layer of a material which is diffusion proof and essentially resistant to corrosive chemicals and arranged so as to form an essentially closed space in which the battery unit (330, 430) is arranged, the closed space's walls (313, 340, 413, 440) constituting the battery casing.

7. A battery according to claim 6, **characterized** in that the material which is diffusion proof and essentially resistant to corrosive chemicals is one of the following; stainless steel, preferably 304L according to ASTM, nickel or Cr-Ni steel.

8. A battery according to claim 6 or 7, **characterized** in that the biocompatible material is titanium.

9. A battery according to claim 6, 7 or 8, **characterized** in that the part of the battery casing made of the second layer (313) and the partition wall (340) serve as one battery pole, and an insulated lead-in (341) is arranged in the partition wall (340) for the other battery pole.

10. A battery according to claim 6, 7 or 8, **characterized** in that an insulating layer (460) is arranged immediately inside the battery casing, and insulated lead-ins (441, 442) are arranged in the partition wall (440) to allow connection of the battery.

11. A method for the manufacture of a casing for an active implant according to claims 1-4 or for a battery according to claims 5 to 8, **characterized** in that a first part is formed from a rolled composite plate or sheet comprising at least two layers, the first layer being made of a biocompatible material and the second layer made of a material which is diffusion-proof and essentially resistant to corrosive chemicals, the first part being goblet- or bowl-shaped in which a battery is formed, wherafter said goblet- or bowl-shaped part is hermetically sealed off by a partition and/or battery unit-closing wall through which one or more insulated lead-ins are arranged to allow connection of the battery's poles.

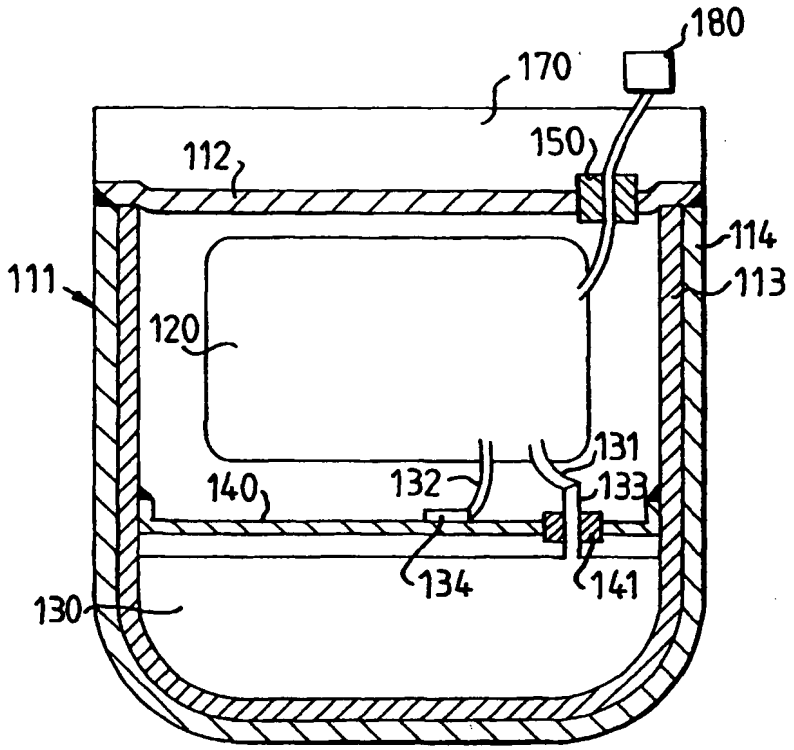
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FIG. 1

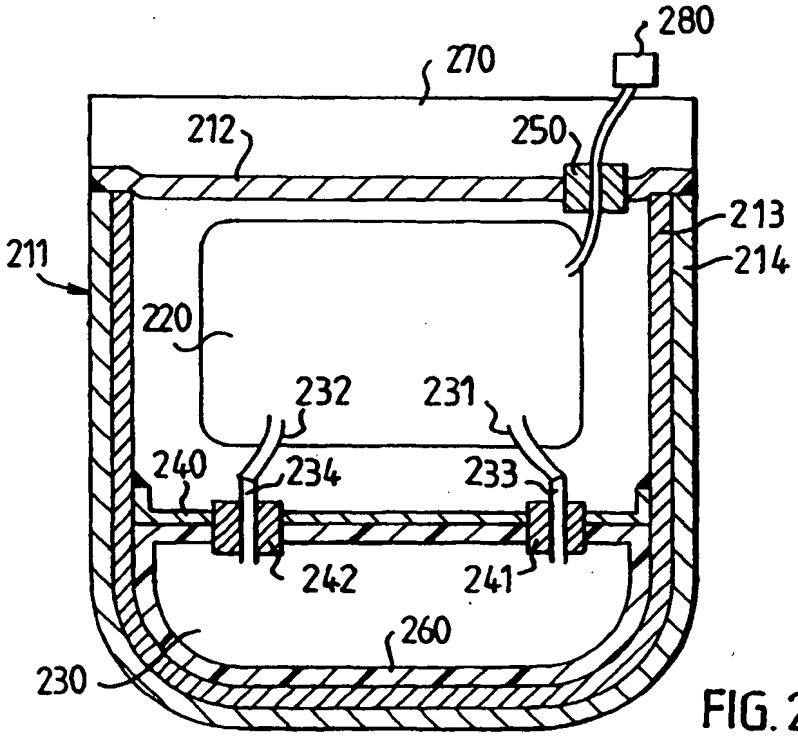
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FIG. 2

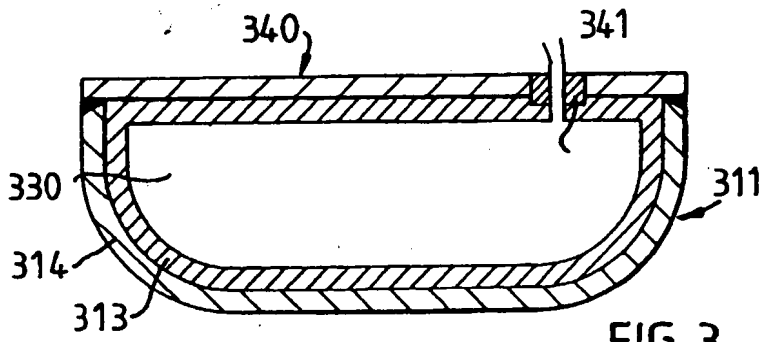

FIG. 3

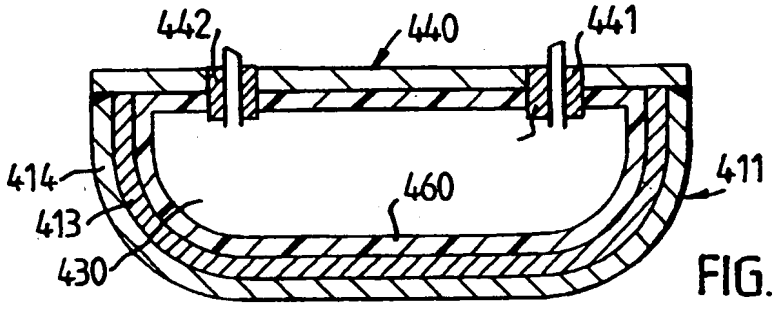

FIG. 4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 10 4360.9

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	GB 2055296 A (MIECZYSLAW MIROWSKI), 4 March 1981 (04.03.81) * page 1, line 78 - line 93; page 2, line 124 - page 3, line 18, abstract *	1-11	A61N 1/375
A	US 5131388 A (BENJAMIN D. PLESS ET AL), 21 July 1992 (21.07.92) * column 3, line 53 - line 56; column 4, line 38 - line 40 *	1-11	

TECHNICAL FIELDS SEARCHED (Int. Cl.6)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	1 July 1997	ANNELI JÖNSSON

CATEGORY OF CITED DOCUMENTS

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